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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/055,364	01/23/2002	Clive Patience	61750-379	9994

7590

06/22/2004

CARELLA, BYRNE, BAIN, GILFILLAN,
CECCHI, STEWART & OLSTEIN
6 Becker Farm Road
Roseland, NJ 07068

EXAMINER

FOLEY, SHANON A

ART UNIT PAPER NUMBER

1648

DATE MAILED: 06/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/055,364

Applicant(s)

PATIENCE, CLIVE

Examiner

Shanon Foley

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2003 and 29 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 5-11 and 15-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 12-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/10/3.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1648

DETAILED ACTION

Applicant timely responded to the restriction requirement on September 26, 2003.

Applicant also reiterated the election on January 29, 2004 in response to an erroneous letter of non-responsiveness by the Office. However, due to subsequent inadvertent clerical errors upon receipt of Applicant's last communication, the Office has not timely responded to the election. The examiner regrets any inconvenience applicant experiences due to this delay.

The examiner acknowledges amendments to the specification, i.e. the continuing data in the first line of the specification, deletion of the hyperlink on page 38, line 15, corrected sequence listing and Figure 11 designations, submitted by Applicant on January 23, 2002.

Election/Restrictions

Applicant's election with traverse of group I in the reply filed on September 26, 2003 is acknowledged. The traversal is on the ground(s) that group I should be joined with claims 6-8 of group III because the antibodies bind to the polypeptides and therefore, would present in any art disclosing the peptides. Applicant further argues that the search for antibodies and polypeptides can be searched together.

Applicant's traversal as been fully considered, but is not found persuasive because as stated in the restriction requirement, the polypeptide of group I and the antibody of group III are structurally and functionally distinct. Neither requires the other for production and use. Further, these groups are separately classified in the art. Therefore, the search for the polypeptide and the antibody are not coextensive.

Claims 5-11 and 15-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking

Art Unit: 1648

claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 26, 2003. Claims 1-4 and 12-14 are under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 and 12-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polypeptide that “binds” with antibodies induced by porcine gamma herpesvirus, does not reasonably provide enablement for an isolated polypeptide that “reacts” with antibodies induced by porcine gamma herpesvirus. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are drawn to an isolated polypeptide comprising an amino acid sequence with at least 80-100% sequence similarity with SEQ ID NO: 24, wherein the polypeptide “reacts” with antibodies induced by porcine gamma herpesvirus. The claims also encompass the polypeptide in a vaccine and a method of immunizing a pig against porcine gamma herpesvirus by administering the polypeptide. The instant polypeptide claimed is not described in the specification in such a way that provides support for chemical reaction between the polypeptide and antibodies induced by porcine gamma herpesvirus. “React”, according to *Dorland's Illustrated Medical Dictionary*, 28th edition. WB Saunders Company; Philadelphia. 1994, page 1426, is a response to a stimulus or “to enter into a chemical action”. Alternatively, the dictionary citation of “bind” means to form a weak, reversible chemical bond, such as with an

Art Unit: 1648

antigen to an antibody, see page 198 of *Dorland's Illustrated Medical Dictionary*. There is no indication that a chemical action takes place between the polypeptide and an antibody from gamma herpesvirus in the disclosure. The instant polypeptide is not enabled for a chemical reaction because there is no way to measure the end point of the chemical reaction. To overcome this rejection, it is suggested that applicant exchange "react" with "bind" in claim 1. Support for "bind" is found for example on page 5, lines 10-12 of the instant disclosure.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13 and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 13 is drawn to a vaccine comprising an immunologically effective amount of a polypeptide having 80% to 100% sequence identity with SEQ ID NO: 24 and that also binds to antibodies induced by porcine gamma herpesvirus. Claim 14 is drawn to a method of immunizing a pig against a porcine gamma herpesvirus by administering the vaccine of claim 13. The nature of the invention is drawn to treating and preventing porcine gamma herpesvirus in pigs. However, while Fishman (*Xenotransplantation*. 2000; 7: 93-95) teaches that porcine gamma herpesvirus is a concern in allotransplantation (see the last full paragraph on page 94), Woodland et al. (*Viral Immunology*. 2001; 14 (3): 217-226) indicate that there is no known vaccine for gamma herpesviruses. Woodland et al. review a murine gamma herpesvirus animal

Art Unit: 1648

model that is used in studies to test and analyze various vaccine strategies against gamma herpesviruses. Woodland et al. teach that the requirements of an effective vaccine against gamma herpesviruses are poorly understood. The working examples of the instant disclosure demonstrate isolation and sequence analysis of porcine gamma herpesvirus glycoprotein B (gpB). However, there are no working examples provided for administering the glycoprotein or evaluating ameliorative properties in pigs with porcine gamma herpesvirus and/or evaluating the prophylactic properties in pigs without viral infection. There is also no indication that administration of the gpB polypeptide would provide the efficacious vaccine that is still currently elusive for treating and preventing gamma herpesvirus infection, according to the teachings of Woodland et al. For these reasons, it is determined that an undue quantity of experimentation would be required of the skilled artisan to make a vaccine comprising gpB or use a the instant composition in a method of immunizing a pig against porcine gamma herpesvirus.

Allowable Subject Matter

The prior art does not teach or suggest an isolated polypeptide comprising an amino acid sequence that has at least 80% to 100% sequence identity to SEQ ID NO: 24, wherein the polypeptide binds with antibodies induced by porcine gamma herpesvirus. Therefore, claims 1-4 and 12 would be allowable if applicant exchanges "react" in line 2 of claim 1 with "bind". Claim 12 requires the polypeptide in a pharmacologically acceptable carrier. Since gpB is disclosed as an envelope viral protein (see page 4, lines 15-19) that generates antibodies against porcine gamma herpesvirus (see page 11, lines 22-25), it is determined that the instant polypeptide in a pharmacologically acceptable carrier would induce an antibody response in a pig against porcine gamma herpesvirus.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Shanon Foley
Patent Examiner, 1648